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College of Medicine and Health Sciences

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Glycemic control and its associated factors among glucometer user and non-user diabetes mellitus patients at Ayder Comprehensive Specialized Hospital, Mekelle, Northern, Ethiopia

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ABBREVIATIONS

ADA	American Diabetics Association
ACSH	Ayder Compressive Specialized Hospital
AOR	Adjusted Odds Ratio
CI	Confidence Interval
COR	Crude Odds Ratio
DM	Diabetes Mellitus
FBG	Fasting Blood Glucose
HbA1c	Glycated Hemoglobin A1
HDL	High Density Lipoprotein
IDF	International Diabetes Federation
LDL	Low Density Lipoprotein
OGTT	Oral Glucose Tolerance Test
POCT	Point of Care Testing
SD	Standard Deviation
SMBG	Self-Monitoring of Blood Glucose
SPSS	Statistical Package for Social Sciences
WHO	World Health Organization

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ABSTRACT

Background: Diabetes is one of the largest health emergencies of the twenty-first century globally. The development of long-term complications is influenced by hyperglycemia and poor glycemic control of diabetes mellitus could accelerate their progression. For provision of standard care for the patients, objective information regarding the magnitude of poor glycemic control is needed

Objective: To assess glycemic control and its associated factors among glucometer user and non-user diabetes mellitus patients at Ayder comprehensive specialized hospital, Mekelle, Northern Ethiopia.

Methods: Institution based comparative cross-sectional study was conducted from March 1 to April 30, 2017. The participants were enrolled in the study by using quota sampling technique. A structured questionnaire was used to collect socio demographic data and other relevant clinical characteristics. Glycated Haemoglobin A1c, Serum fasting blood sugar and lipid profile were determined using HumaMeter A1c (HUMAN, Germany) and ABX PENTRA 400 clinical chemistry analyzer (HORIB ABX Diagnostics, France). Data was analyzed using Statistical Package for Social Sciences version 20. Independent t-test, binary and multiple logistic regression analysis were used. P-value <0.05 and corresponding 95% confidence interval were considered for statistically significance.

Result: A total of 336 Diabetes mellitus participants participated in this study, of these, 168 (50%) were glucometer users and the rest were non-users. Overall 208(61.9%) of the study participants had poor glycemic control. The poor glycemic control was significantly higher in non-glucometer user 120(71.4%) compared to glucometer user 88(52.4%) (P-value <0.001). The mean HbA1C was significantly higher among non-users than glucometer users (8.4 ±2.24 vs. 7.68 ±1.95) (p-value<0.001). It was found that age, income, the number of visits, the level of high triglyceride, the level of high low-density lipoprotein and non-glucometer use were significantly associated with the poor glycemic control.

Conclusion: Glucometer use is associated with lower HbA1c and decreased odds of having poor glycaemic control compared to non-glucometer user. Therefore, SMBG recommended to facilitating better glycemic control.

Key words: *Diabetes Mellitus, Glucometer, Glycemic control, Self-monitoring blood glucose*

1. INTRODUCTION

1.1 Background

Diabetes mellitus (DM) is a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism, resulting from defects in insulin secretion, insulin action, or both (1). The majority of cases of DM fall into two broad categories: type 1 and 2 DM. Type 2 DM, which accounts for ~90–95% of those with DM, encompasses individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency (1, 2). Type 1 DM is characterized by an absolute deficiency of insulin secretion caused by pancreatic β- cell destruction, usually resulting from an autoimmune attack. It accounts for approximately 10% of all cases (3).

The prevalence of both type 1 and type 2 DM is increasing worldwide. Type 2 DM is rising much more rapidly, presumably because of increasing obesity, reduced physical activity levels as countries become more industrialized, and the aging of the population (4). According to International Diabetes Federation(IDF) DM Atlas 2015 report, more than 75% of people with DM live in low and middle income countries (5). In Africa region DM is expected to be the highest in the future time. It also reported 3.8% regional prevalence of DM and will rise to 4.3% in 2030. Cases of DM in Ethiopia has estimated about 1.4 million and prevalence of 3.32% (6).

To lower blood glucose levels for DM patients, management of diet, injection of insulin, and oral medication are currently available. Patient education and self-care practices are also important aspects of disease management that help patients with DM to lead normal lives (7).

American Diabetes Association (ADA) recommends routine self-monitoring blood glucose (SMBG) for DM patients (8). It is an important component of modern therapy for DM. Self-monitoring of glycemic control is a cornerstone of DM care that can ensure patient participation in achieving and maintaining specific glycemic targets. The most important objective of monitoring is the assessment of overall glycemic control and initiation of appropriate steps in a timely manner to achieve optimum control (9).

Glycated hemoglobin (HbA1c) is one of the Glycated hemoglobins, a subfraction formed by the attachment of various sugars to the Hb molecule. HbA1c is formed in two steps by the non-enzymatic reaction of glucose with the N-terminal amino group of the β-chain of normal adult Hb (HbA). The first step is reversible and yields labile HbA1c. This slowly rearranges in the second reaction step to yield stable HbA1c. In the erythrocytes, the relative amount of HbA converted to stable HbA1c increases with the average concentration of glucose in the blood. The conversion to stable HbA1c is limited by the erythrocyte's life span of approximately 100 to 120 days. As a result, HbA1c reflects the average blood glucose level during the preceding 2 to 3 months. It is thus suitable to monitor long-term blood glucose control in individuals with DM. More recent glucose levels have a greater influence on the HbA1c level (10). The ADA recommendation of optimal glycemic control in DM patients is HbA1c level of <7% (2).

Different researchers had shown that poor glycemic control of DM patients leads to microvascular and macrovascular complications (11-13). However, lowering HbA1 concentrations (by tight glycemic control) significantly reduces the rate of progression of microvascular complications. For instance, dropping HbA1 from 9.1–7.3 % reduces the risk of macrovascular disease by 41 %, retinopathy by 63%, neuropathy by 60 %, and nephropathy by 54 %. Every increase in HbA1 can increase the cardiovascular event rate by up to 18 % and the microvascular event rate by up to 30 % (11-13).

The use of SMBG was associated with decrease in HbA1c levels only when the results of SMBG were utilized to modify therapeutic regimens (14). In clinical practice, many barriers can be responsible for a reduced effect of SMBG in patients not taking insulin. In fact, the patient is supposed to learn accurate and reliable monitoring skills, proper interpretation of the results, and how to use the results to adjust medical nutrition therapy, exercise, and pharmacologic therapy to achieve specific glycemic goals (15). Unfortunately, many patients either are not taught the self-management skills required lowering the measured glucose values, or they are not able to act on self-monitoring results. As a consequence, self-monitoring

can be associated with discomfort, poor acceptance of the disease and increased worries about the consequences of diabetes (16).

The underutilization of the information deriving from self-monitoring also precludes the possibility of targeting and monitoring postprandial hyperglycaemia, an essential determinant of metabolic control and diabetes complications (17). From an economical perspective, the costs of blood glucose monitoring are considerable (18). In order not to waste resources, it is important that people with diabetes are able to utilize home monitoring effectively through diabetes education. Without this education to know when and how to test, and what to do with the results, home monitoring can fail to produce the expected benefits.

A major advantage of Point of Care Testing (POCT) is, it can be used in any setting, easy to operate, use of minimal blood volumes and provides immediate results (19). Furthermore, data downloaded from glucometers can be used in conjunction with written records in log books to evaluate glucose patterns and formulate more precise and efficacious therapeutic regimens (20). Therefore the aim of this study is to assess glycemic control and its associated factors among glucometer user and non-user DM patients as a POCT.

1.2 STATEMENT OF THE PROBLEM

Diabetes is undoubtedly one of the largest health emergencies of the twenty-first century. A worldwide prevalence of 8.5% in 2015 (21), which is predicted to reach 642 million by 2040. The largest increase will take place in regions where economies are moving from low to middle income levels. About 75% of people with DM live in low and middle income countries (5).

The magnitude of poor glycemic control in DM patients in different parts of the world is high. For instance, a study conducted in Malaysia showed 75.3 %, in Spain 45 %, in Jordan 65.1 % and in Ethiopia 94 % (22-25). Different studies indicated that there are many contributing factors to poor glycemic control. These include older age, female sex, ethnic variation, drinking alcohol, higher BMI, smoking, longer duration of DM, lower physical activity, lack of adherence to diabetes management (such as diabetes self-care management), and many others (22, 26).

Access to standard DM management in sub-Saharan Africa (SSA) was extremely limited because of insufficient healthcare systems; scarcity of professionals with satisfactory training in DM diagnosis and treatment; scarcity or unaffordability of medication, glucometer strips and scarcity of diagnostic tools and other equipment (27, 28). Moreover, health care in SSA is epidemiologically known with a high burden of communicable diseases and scarcity of financial and human resources. DM presents an additional challenge by accounting for the 75% of deaths in people due to DM under the age of 60 annually (6, 29).

The cost of treatment and death of DM arise mainly from its complications, such as heart diseases, stroke, amputations, kidney failure and serious infections. These can be prevented or long-delayed by inexpensive, patient self-care practice by monitoring their blood sugar, blood pressure level, quit smoking and alcohol and practice that reduces bad cholesterol and by adopting a healthy diet and exercise (29, 30).

Poor glycemic control is the most common cause of hospital admissions and complications in DM (5, 31). Evidence shows that maintaining good glycemic control is a main therapeutic goal for all patients with DM to prevent organ damage and other micro-vascular and macro-vascular

complications. Glycemic control, however, is not an easy task for many patients. It is well known that even in clinical trials, and routinely in clinical practice, the majority of patients fail to achieve good glycemic control (31).

Different studies showed that good glycemic control is achieved in less than 50% of DM patients (22-25). The reasons for this failure are complex and multi factorial of which both patient and healthcare provider related factors may contribute to poor glycemic control (32). However, proving exactly what factors lead to the loss of glycemic control can be challenging. Studies with DM patients have found correlations between poor glycemic control and factors such as socio demographic characteristics, insulin therapy, knowledge and skill deficit, poor adherence to insulin regimen, self-care, exercise and dietary plan combined with the poor interaction between the patient and health care providers (33). Significant knowledge and skill deficits have been found among 50–80% of DM patients who failed to achieve good glycemic control (34).

For provision of standard care for the patients, objective information regarding the magnitude of poor glycemic control is needed; however, studies on the assessment of glycemic control using HbA1c in Ethiopia are very scarce. Limited research done on glycemic control and its associated factors among glucometer user and non-user DM patients in the study area. Therefore, the finding of this study will fill the information gap about glycemic control and its associated factors among glucometer user and non-user DM patients as a POCT.

1.3 LITERATURE REVIEW

1.3.1 Proportion of Glycemic Control

One of the primary goals of DM management is to lower blood glucose levels because it is well established that improved glycemic control delays the onset and retards the progression of microvascular and macrovascular complications (35). As such, regular testing of blood glucose is a cornerstone and achievement of adequate glycemic control is a goal for proper DM care (36).

A cross-sectional study conducted in India to assess factors associated with a poor glycemic control in Type 2 DM patients. Poor glycemic was observed in 78.6% (37). Different figures were reported for poor glycemic control by similar studies conducted in Jordan 65.1% (38), Saudi Arabia 78% (39), Cameroon and Guinea 74% (40) and Tanzania 69.7% (41).

A longitudinal study conducted on the role of self-monitoring of blood glucose and intensive education in patients with Type 2 DM not receiving insulin in Italy. The study showed that the proportion of poor glycemic control was 38.1% among participants performed SMBG and 80% among participants non performed SMBG (had HbA1c $\geq$ 7%) (42).

A Cross-sectional study conducted on the relationship between self-monitoring of blood glucose and glycemic control among patients attending a specialist DM clinic in Jamaica. The finding showed that 52.5% Patients performing SMBG and 61.9% Patients not performing SMBG had HbA1c $\geq$ 7% (43).

A cross-sectional study conducted on factors associated with poor glycemic control among patients with Type 2 DM in Jordan. The study estimated the proportion of patients with Type 2 DM who did not achieve a target level of HbA1c. Poor glycemic control (HbA1c $\geq$7%) was present in 65.1% of patients. The proportion of poor glycemic control among participants performing SMBG and participants not performing SMBG were 51.1% and 73.8 respectively (26).)

A cross-sectional study conducted in Gonder Referal Hosptal, Ethiopia, to assess Level of sustained glycemic control and associated factors among patients with DM. Poor glycemic control was observed in 64.7% of the patients had HbA1c ≥7%) (44). A similar study conducted in Jima, Ethiopia reported 58.2% (45) and a study conducted among patients with type 2 DMin Ambo Hospital, Ethiopia, which showed 50% of the participants were poor glycemic control (46).

1.3.2 Factors Associated with Glycemic Control

A retrospective cohort study conducted in Germany has shown which DM patients in non-SMBG subgroup were associated with poor glycemic control and chronic complications (47). Various studies also support, in which SMBG has been shown to be associated with better glycemic control, improved medication compliance and increased the frequency of visit to health institution (47, 48).

A cross-sectional study carried out among type 2 DM patients in India and observed that male sex was found to be a risk factor for poor glycemic control (49). Low level of education was also another factor which negatively affects blood glucose control among DM patients (49).

A cross-sectional study conducted to assess the determinants of loss of glycemic control among patients with DM in Basrah, Iraq. In the study, the less educational level was found to be one of the contributing factors for poor glycemic control (50). The result was also supported by similar studies carried out in Jordan (38), and Spain (51).

A Prospective cohort study conducted to assess determinants of loss of glycemic control in patients with type 1 DM in Iraq. The study found that lower age to be a contributing factor to poor glycemic control (50). Similar results were reported in Patient characteristics do not predict poor glycemic control in type 2 DM patients treated in primary care in Netherlands (52) and a longitudinal study conducted in Predictors of glycemic control among patients with Type 2 DM in San Diego, USA (53).

A cross-sectional study conducted to assess the association between DM metabolic control and drug adherence in an indigent population in Virginia, USA revealed that better metabolic control was independently associated with increasing age (54). Similar findings were also observed in another USA study conducted in Medication adherence and achievement of glycemic targets in ambulatory type 2 DM patients (55).

A cross-sectional study conducted on factors associated with poor glycemic control among patients with type 2 DM in Jordan. The study found that poor glycemic control was more common among patients who did not practice any physical activity (38). Similarly, a study conducted on Medication adherence and achievement of glycemic targets in ambulatory type 2 DM patients in the USA, on the other hand, revealed that an increase in physical activity was found to be associated with a decrease in HbA1c levels of more than 1 percentage point (55). This was supported by studies and reports coming from Canada a controlled clinical trials on Effects of exercise on glycemic control and body mass in type 2 DM (56) and a similar study conducted in the USA on exercise and 24-h glycemic control: equal effects for all type 2 DM patients (57).

A cross-sectional study conducted to assess dyslipidemia among DM patients in Hawssa, Southern Ethiopia. The study found that, higher mean serum levels of LDL cholesterol, total cholesterol, and triglycerides were significantly associated with a poor glycemic control in patients with diabetes, which are well known risk factors for CVD among DM patients (58). Similarly, study conducted in Jordan found that DM was more likely to be poorly controlled among those with increased duration of DM, lower level of education, higher BMI, hypercholesterolemia, hypertriglyceridemia, and elevated LDL (59). But was not consistent with cross sectional population study finding from the UK (60).

A hospital based cross-sectional study conducted in Hawassa South Ethiopia, 2013; the study revealed that DM patients who did not perform self-monitoring of blood glucose were 15.22 times more likely to have chronic complications than those who performed self-monitoring of

blood glucose. The study participants perform SMBG once per week and most of them were insulin treated DM patients (61)

A cross-sectional study conducted to assess Self-Care behavior among Patients with DM in Harari, Eastern Ethiopia. The study found that income was one of the factors that affect self-care behavior and lead to poor glycemic control. High and medium income patients were less adherent to self-care than low income patients; this may be due to high income patients may have riskier life style than low-income respondents (62).

A cross-sectional study conducted to assess level of sustained glycemic control and associated factors among patients with DM in Gonder, Ethiopia. The study reported follow-up visit for the last 6 months showed that increased frequency of hospital visits was negatively associated with poor glycemic control (AOR =0.13; 95% CI =0.03, 0.59) among persons with Type 2 DM (44).

Generally, in different kinds of literatures Poor glycemic control was found to be associated with sex, age, body mass index, hypertension, dyslipidemia, and duration of DM. Also, the glycemic level of the patients was possibly affected by self-management behaviors such as diet, exercise, and SMBG.

1.4 SIGNIFICANCE OF THE STUDY

This study provides information about the current glycemic status of both glucometer user and non-glucometer user DM patients. This may allow for assessment of therapy and guiding adjustments in diet, exercise, and medication in order to achieve optimal glycemic control. This study also helps DM patients to improve the practical behaviors, testing blood glucose levels at home or SMBG is a valuable diabetes management tool. The study also facilitates regular testing and recording of blood glucose level that can help for DM patients to monitor the effects of healthy lifestyle choices.

Moreover, this study provides evidence for evaluating how the DM patients control or monitor their blood glucose level activity depending on the laboratory tests; Due to these DM patients adjust their treatment plan and better control on management of DM. In addition to these, information generated from this study uses for interested bodies for further investigation to develop appropriate preventive and control strategy. Finally, Ayder Compressive Specialized Hospital and others health institutions can use this result for improving their services for DM patients. It also helps to encourage good services and expand their services especially laboratory facilities like HbA1c tests.

2. OBJECTIVE

2.1 General objective

- To assess Glycemic control and its associated factors among glucometer user and non-user DM patients at Ayder Comprehensive Specialized Hospital, Mekelle, Northern Ethiopia.

2.2 Specific objectives

- To assess the overall prevalence of poor glycemic control among DM patients
- To compare glycemic control of DM patients between glucometer user and non-user as POCT
- To identify associated factors of poor glycemic control among DM patients

Hypothesis

There is a difference in glycemic control among glucometer user and non-user DM patients as POCT.

3. MATERIALS AND METHODS

3.1 Study area

This study was conducted in Mekelle town, Tigray region, Northern part of Ethiopia. It is located around 780 kilometers from Addis Ababa, the capital city of Ethiopia. Based on the 2009 Census conducted by the Central Statistical Agency of Ethiopia, this town has a total population of 215,914 people (104,925 men and 110,989 women).The city has one referral hospital , three general hospitals, nine health centers and several private clinics and for-profit hospitals. The study was conducted at Ayder comprehensive specialized hospital, which is the second largest hospital in Ethiopia. It has 500 beds. It serves up to 8 million populations in its catchment areas of the Tigray region, North-eastern Amhara and Northern Afar regions. The hospital became functional before 8 years ago. It has four major departments and other specialty units. DM ambulatory clinic unit is one of the specialty units of the hospital, which provides medical services for registered DM patients. It also serves as a teaching hospital of the College of Health Sciences which was established under Mekelle University in 2003.

3.2 Study design and period

A prospective comparative cross-sectional study was conducted on DM patients from March 1 to April 30, 2017.

3.3 Population

3.3.1 Source population

All adult type I and type II DM patients following their medical care in Ayder Comprehensive Specialized Hospital.

3.3.2 Study population

All type I and type II DM patients ≥ 18 years old on follow up who fulfill the inclusion criteria in Ayder Comprehensive Specialized Hospital that visited DM clinic during the study period.

3.4 Inclusion criteria

All type I and type II DM patients aged ≥18 years and who were glucometer user and non-glucometer user as POCT. Patients using glucometer as POCT ≥ 6 months were also included in the study as adequate time needs for assessing adherence.

3.5 Exclusion criteria

- Critically ill patients and unable to participate in the interview
- Patients with severe mental illness
- Newly diagnosed DM patients
- Other chronic diseases (Thyroid dysfunction, AIDS, Liver problem)

3.6 Variables

3.6.1 Dependent variable

- Glycemic control

3.6.2 Independent variables

- Socio-demographic: age, sex, educational status, occupation, income, marital status, residence, and family history of DM
- Clinical characteristics and others associated factors: type of DM, duration of DM, type of treatment, Blood pressure, lipid profile, Body Mass Index, alcohol consumption, cigarette smoking and frequency of visiting in DM clinics.

3.7 Sample size and sampling technique

The sample size was determined using the difference between two population means with specified precision by OpenEpi version 2.3 statistical software formula based on the following assumptions: the mean and SD of SMBG and non-SMBG group HbA1c were (9.5,2.4) and (10.5,3.1) respectively from a study conducted in the USA (63). The desired degree of precision was 5%, 95% confidence interval and for 90% power value is 1.28. An equal number of the sample was taken from each glucometer users and non-glucometer users. So that a total

sample was (168+168) = 336. Both glucometer users and non-users DM patients were enrolled in the study by using age and gender matched quota sampling technique.

3.8 Data collection and laboratory methods

Patients were given an orientation on the protocol and specific details concerning participation in the study. Data was collected by trained nurses; interviewing eligible participants using a pretested and structured questionnaire. The questionnaire includes questions intended to collect data about socio-demographic characteristics and clinical characteristics. Anthropometric measurements were taken using standardized techniques and calibrated equipment by trained nurses. Patients were weighed to the nearest 0.1 kg. Height was measured using a stadiometer. Every patient was made aware of the fasting requirement for a minimum of 8 hours prior to the laboratory test. Verbal confirmation was obtained prior to the blood test. Information about Type 1 and Type 2 DM was collected from the hospital chart by data collector nurse.

Five milliliters of venous blood was drawn from each volunteer patient using a disposable plastic syringe by senior laboratory technologist. About two milliliters of venous blood poured into EDTA test tube for the determination of HbA1c. The HbA1c was measured by HumaMeter A1C analyzer (HUMAN Diagnostics, Germany). About three milliliters of venous blood poured into Serum Separate Test tube and then centrifuged after it has been clotted. Serum was kept in the refrigerator till used. Serum FBS and lipid profile were measured by ABX PENTRA 400 clinical chemistry analyzer (HORIB ABX Diagnostics, France), according to the manufacturer's procedures in ACSH central laboratory.

Method

GOD-PAP Enzymatic Colorimetric (HORIB ABX Diagnostics, France) and CHOD-PAP Enzymatic Colorimetric (HORIB ABX Diagnostics, France) methods were used for determination of blood glucose and lipid profiles, respectively.

Principle for determination of HbA1c

The Humameter A1c regent KIT combines the chemical binding of boronate to glycated hemoglobin with the fluorescent quenching effect that this binding exerts on a fluorescent marker bound to the boronate molecule. The total hemoglobin concentration is determined from the initial decrease in the fluorescent signal. The fluorescent boronate conjugate binds to the glycated hemoglobin, which is measured by monitoring a decrease in the fluorescence of the active ingredient. The ratio of glycated hemoglobin to total hemoglobin is determined and the result is presented in up to two user selectable units: % DCCT (Diabetes control & complication Trial),mmol/mol IFCC (international Federationof clinical Chemistry).

Mmol/mol= (% DCCT-2.15)*10.929

In accordance with ADA guidelines, glycemic status was categorized as good glycemic control if HbA1c <7% and poor glycemic control if HbA1c ≥7% (64), abnormal lipid profile was defined as Total Cholesterol ≥200 mg/dl, HDL-c <40mg/dl for male, HDL-c <50 mg/dl for female, LDL-c ≥130 mg/dl, and Triglyceride ≥150mg/dl (64).

3.9 Data management and quality control

Two nurses and two medical laboratory technologists together with the principal investigator were involved in the data collection. One of the laboratory technologists with principal investigator acted as supervisor. Both the data collectors and supervisor were trained for one day to keep uniformity of the data collection process, blood specimen collection, processing, and analysis. Before actual data collection, the questionnaire was pre-tested on 5% volunteer patients to check clarity, acceptability, and consistency of the structured questionnaire in Qiuha hospital. Necessary corrections were taken before the actual data was collected. Blood samples that passed acceptable criteria by the laboratory Standard Operational Procedure were included in the study.

To produce quality results, the standard operation procedure and manufacturer's instructions were strictly followed. All samples were analyzed by senior medical laboratory Technologist. The automation was calibrated using an appropriate calibrator. Quality control materials (Control N and Control P) were run at least once each day to verify each procedure. The

frequency of quality controls and the confidence intervals were corresponding to laboratory guidelines. The results were within the range of the defined confidence limits (within ±2SD). For those results were out of these confidence limits, the laboratory personnel were taken corrective action based on established procedure before reporting.

3.10 Data analysis and interpretation

All the data was cleaned, edited, coded and analyzed using SPSS version 20 statistical package. Frequencies and cross tabulations were used to summarize descriptive statistics. Independent t-tests were used to compare the mean of Clinical characteristics between glucometer user and non-user of study participants. Categorical and continuous variables were described as proportions and mean respectively. Multivariable logistic regression analysis was employed by selecting only variables with P-value <0.2 in the bivariate analysis. A multivariable logistic regression analysis was done to see the association between the independent variable and outcome variables. Odds ratio with 95% C.I was used for measuring the strength of association. P value < 0.05 was used to determine level of statistical significance

3.11 Result dissemination plan

The result of the study will be disseminated to Ayder comprehensive specialized hospital, Regional and zonal health office and also to the University of Gondar, College of Medicine and Health Sciences, School of Biomedical and Laboratory Sciences, Department of Clinical Chemistry. Results of this study will be disseminated through publication, presentation on annual scientific conferences and seminars.

3.12 Ethical consideration

Ethical clearance was obtained from Ethical Review Committee of School of Biomedical and Laboratory Sciences, University of Gondar. Permission was obtained from Ayder Comprehensive Specialized Hospital medical director to conduct the study. After informing about the objective of the study and the confidentiality of the data, written consent was taken from all study participants. To ensure confidentiality of data, study participants were identified using codes and unauthorized persons were not having access to the collected data.

3.13 Operational definition

- **Hypertension:** defined as People with systolic/diastolic blood pressure levels ≥130/80 mmHg or who were on antihypertensive medication.
- **Body mass index:** categorized as if underweight if BMI<18 Kg/m^2, normal if BMI was 18-25 kg/m2, overweight if BMI was 25–29.9 kg/m2, and obese if BMI was ≥30 kg/m2
- **Good glycemic control**: defined as HbA1c <7%
- **poor glycemic control:** defined as HbA1c ≥7%
- **Abnormal lipid profile:** defined as Hypercholesterolemia refers to a total cholesterol level ≥200 mg/dl. HDL was considered low when the level is <40 mg/dl in males and <50 mg/dl in females. LDL was considered high when the level is ≥130 mg/dl. Hypertriglyceridemia refers to a level ≥150 mg/dl.
- **Low income:** respondents whose income level is below the 25% Inter-Quartile percentiles (IQP)
- **Medium income:** defined as whose income level is between 25% -75% IQP
- **High income**: defined as respondents whose income level is equal to or above the 75% IQP
- **Self-monitoring blood glucose** (glucometer user): defined as participants performed home glucose monitoring for 5 days or more per week and at least check their blood glucose level once per day at home for the last 6 months.
- **Non-glucometer user:** defined as participants not performed home glucose monitoring (no their own glucometer).

4. RESULT

4.1 Socio demographic characteristics of study participants

A total of 336 DM participants participated in this study; of these, 168 (50%) were glucometer users and the rest were non-users. One hundred sixty (47.6%) were at the age range of 45-64 years. The mean age of participants were 49.25(±16.3) and 48.76(±15.9) among glucometer users and non-users respectively. The majority, 311 (92.6%) of study participants were urban residents; 139 (41.4%) were educated college and above level; 106 (31.6%) of participants were government employees and 163 (48.5%) had medium monthly income (Table 1).

Table 1: Socio-demographic characteristics of study participants in Ayder Comprehensive Specialized Hospital, Mekelle, Ethiopia, 2017 (n=336)

Variables	Glucometer			
	User	Non-user:	Total:	
	n (%)	n(%)	n (%)	P. value
Age(years)				
<25	23(13.7)	23(13.7)	46(13.7)	
25-44	36(21.4)	34(20.2)	70(20.8)	
45-64	79(47.0)	81(48.2)	160(47.6)	.994
65+	30(17.9)	30(17.9)	60(17.9)	
Sex				
Male	89(53.0)	88(52.4)	177(52.7)	1.00
Female	79(47.0)	80(47.6)	159(47.3)	
Residence				
Urban	162(96.4)	149(88.7)	311(92.6)	.013*
Rural	6(3.6)	19(11.3)	25(7.4)	
Educational status				
Unable to read and write	12(11.9)	29(17.3)	41(12.2)	
Write and read	10(6.0)	7(4.2)	17(5.1)	
Primary	30(17.9)	29(17.3)	59(17.5)	.008*
Secondary	34(20.2)	46(27.4)	80(23.8)	
College and above	82(48.8)	57(33.9)	139(41.4)	
Occupation				
Student	20(11.9)	21(12.5)	41(12.2)	
Government employee	59(35.1)	47(27.9)	106(31.6)	.029*
Private	19(11.3)	31(18.5)	50(14.9)	
Merchant	20(11.9)	8(4.8)	28(8.3)	
Unemployed	14(8.3)	13(7.7)	27(8.0)	
Housewife	24(14.3)	23(13.7)	47(14.0)	
Monthly income				
Low	33(19.6)	56(33.3)	89(26.5)	<0.001*
Medium	77(45.8)	86(51.2)	163(48.5)	
High	58(34.5)	26(15.4)	84(25.0)	
Has family history of DM				
Yes	55(32.7)	36(21.4)	91(27.1)	. 027*
No	113(67.3)	132(78.6)	245(72.9)	
Marital status				
Single	28(16.7)	26(15.5)	54(16.1)	
Married	105(62.5)	120(71.4)	225(67.0)	.247
Divorced	16(9.5)	11(6.5)	27(8.0)	
Widowed	19(11.3)	11(6.5)	30(8.9)	

4.2 Clinical characteristics and anthropometric measurements of study participants by glucometer use

Overall 208(61.9%) of the study subjects had poor glycemic control. The poor glycemic control was significantly higher in non-glucometer user 120 (71.4%) than glucometer user 88 (52.4%) (P-value <0.001).

About 264 (78.6%) were type-II DM subjects. More than half of males 98 (55.4%) had low value of high-density lipoprotein (HDL). About 198(58.9%) study subjects had average FBS ≥130mg/dl (P-value=0.020 and 210(62.5%) study subjects were visited DM clinics greater than or equal to 6 times within six months (P=0.032). (Table2).

Table 2: Clinical characteristics of study participants in Ayder Comprehensive Specialized Hospital, Mekelle, Ethiopia, 2017 (n=336)

Variables	Glucometer			
	User	Non-user	Total:	
	n(%)	n(%)	n(%)	P. value
Glycemic control				<0.001*
Poor (HbA1c ≥ 7%)	88(52.4)	120(71.4)	208(61.9)	
Good (HbA1c <7%)	80(47.6)	48(28.6)	128(38.1)	
BMI				
Low (<18)	7(4.2)	4(2.4)	11(3.3)	
Normal (18-25)	85(50.6)	106(63.1)	191(56.8)	
Overweight (25-29)	62(36.9)	48(28.6)	110(32.7)	
Obese (>=30)	14(8.3)	10(5.9)	24(7.1)	
Duration of DM				0.913
≤7years	90(53.6)	92(54.8)	182(54.2)	
>7 years	78(46.4)	76(45.2)	154(45.8)	
Number of DM clinic visits				.032*
<6 times / 6 months	53(31.6)	73(43.4)	126(37.5)	
≥6 times/6 months	115(68.4)	95(56.6)	210(62.5)	
Triglyceride				.743
Normal(<150)	93(55.4)	89(53.0)	182(54.2)	
High (≥150)	75(44.6)	79(47.0)	154(45.8)	
Total cholesterol				0.361
Normal (<200)	126(75.0)	134(79.8)	260(77.4)	
High (≥200)	42(25.0)	34(20.2)	76(22.6)	
HDL males (n=177)				0.827
Normal (≥40)	39(43.8)	40(45.5)	79(44.6)	
Low(<40)	50(56.2)	48(54.5)	98(55.4)	
HDL females (n=159)				0.767
Normal (≥50)	8(10.1)	7(8.8)	15(9.4)	
Low (<50)	71(89.9)	73(91.2)	144(90.6)	
LDL				0.482
Normal (<130)	134(79.7)	140(83.3)	274(81.6)	
High(≥130)	34(20.2)	28(16.7)	62(18.4)	
Type of DM				0.894
Type I	37(22.0)	35(20.8)	72(21.4)	
Type II	131(78.0)	133(79.2)	264(78.6)	
Hypertension				0.230
No (<130/80mm/Hg)	78(46.4)	90(53.6)	168(50.0)	
Yes(≥130 /80mm/Hg)	90(53.6)	78(46.4)	168(50.0)	
FBS				0.020*
<130 mg/dl	80(47.6)	58(34.5)	138(41.1)	
≥130 mg/dl	88(52.4)	110(65.5)	198(58.9)	

OHA- Oral Hypoglycemic Agents

4.3 Comparison of the mean of Clinical characteristics of study participants

The mean of HgA1C was significantly higher among non-glucometer users than glucometer users (8.4 ±2.24 vs. 7.68 ±1.95) (p-value<0.001). Likewise, the level of FBS was higher among glucometer non-users (176.2±71.7) than users (152.3 ±65.4) (p-value=0.002). However, the mean BMI was higher among glucometer users (24.6±3.6) than non-users (23.8±3.9) (P=0.047) (Table 3).

Table 3: Comparison of the mean of Clinical characteristics by glucometer use of DM subjects based on independent t-test in Ayder Comprehensive Specialized Hospital, Mekelle, Ethiopia, 2017. (n=336)

Clinical Parameters	**Glucometer**			
	User (Mean ±SD)*	Non-user (Mean± SD)	T**	P-value
HbA1c	7.68±1.95	8. 4±2.24	-3.306	.001
Total Cholesterol	170.8 ±47.7	166.6 ±44.13	0.845	.398
Triglyceride	180.4 ±108.2	175.7 ±95.8	0.422	.674
High density lipoprotein	37.7 ±8.9	37.7 ±8.8	-.049	.961
Low density lipoprotein	95.6 ±34.4	93.9 ±33.9	0.455	.649
Systolic blood pressure	127.7 ±13.1	125.7 ±13.0	1.362	.174
Diastolic blood pressure	77.2 ±8.3	76.7 ±9.2	.528	.598
Duration of DM	7.79 ±4.89	7.87±5.48	0.282	.883
Fasting blood sugar	152.3 ±65.4	176.2±71.7	-3.193	.002
Body mass index	24.6±3.6	23.8±3.9	0 .238	.047

*Mean and standard deviation, **Independent t-test, HbA1c- Glycated Haemoglobin A1c

4.4 Correlation between lipid profiles and Glucose with HbA1c level

Pearson correlation test showed that HbA1c significantly correlate positively with T. cholesterol (r=0.283, P<0.001), Triglyceride (r=0.252, P<0.001), LDL(r=0.254, P<0.001), and glucose (r=0.906, P<0.001). Whereas, negatively correlated with HDL level (r= -0.041, P=0.459) but not significant (Table 4).

Table 4: Pearson Correlation tests between lipid profiles and Glucose with HbA1c level among DM subjects in Ayder Comprehensive Specialized Hospital, Mekelle, Ethiopia, 2017 (n=336).

Variables		T. cholesterol	Triglyceride	*LDL	*HDL	Glucose
HbA1c	Correlation (r) Coefficient	0.283**	0.252**	0.254**	-0.041	0.906**
	P. value	0.000	0.000	0.000	0.459	0.000

**Correlation significant P<0.05, *LDL- Low Density Lipoprotein, *HDL- High Density Lipoprotein

4.5 Factors associated with poor glycemic control

It was found that age, income, the number of visits in DM clinics, the level of triglyceride, level of low density lipoprotein and non-glucometer users were significantly associated with poor glycemic control. Participants who were at age group less than 25 years had higher odds of poor glycemic control compared to greater than or equal to 25 years old. Those who were in medium income category had 2.5 times (AOR=2.5; 95%CI (1.3, 4.89)) higher odds of poor glycemic control than who were on low income category. Participants who were visited DM clinics less than 6 times had 0.55 times(AOR=0.55; 95%CI (0.3, 0.94)) higher odds of poor glycemic control compared to more or equals to 6 times visited in the past six months. Participants with higher triglyceride and LDL level had 2.29 times (AOR=2.29; 95%CI (1.25, 4.2)) and 4.1 times (AOR=4.1; 95%CI (1.48, 11.4)) higher odds of poor glycemic control than normal counterparts (triglyceride<150 and LDL<130) respectively. Non-users of glucometer for self-monitoring had 2.7 times (AOR=2.7; 95%CI (1.58, 4.64)) higher odds of poor glycemic control than those who use a glucometer for self-monitoring (Table 5).

Table **5:** Factors associated with poor glycemic control among DM subjects in Ayder Comprehensive Specialized Hospital, Mekelle, Ethiopia, 2017 (n=336).

Variables	Glycemic control				
	Good: n (%) (HbA1c <7%)	Poor: n (%) (HbA1c≥7%)	COR 95%(CI)	AOR95%(CI)	P.val
Age (years)					
65+	26(43.3)	34(56.7)	1	1	
45-64	62(38.8)	98(61.2)	0.69(0.3, 1.39)*	0.24(0.09,0.6)**	.007
25-44	26(37.1)	44(62.9)	0.74(0.3,1.39)*	0.25(0.09,0.67)**	.010
≥24	14(30.4)	32(69.6)	0.57(0.2, 1.29) *	0.22(0.08,0.61)** .009	
Residence					
Rural	6(24.0)	19(76.0)	1		
Urban	122(39.2)	189(60.8)	2.04(0.7, 5.26)	1.78(0.59,5.3)	.064
Monthly income					
Low	38(42.7)	51(57.3)	1	1	
Medium	51(31.3)	112(68.7)	1.64(0.96, 2.79)	2.5(1.3,4.89)**	.002
High	39(46.4)	45(53.6)	0.86(0.47,1.57)	1.69(0.74,3.81)	.217
Number of visits per last 6 months					
≥6 times	95(45.2)	115(54.8)	1	1	
<6 times	33(26.2)	93(73.8)	0.49(0.2, 0.69) **	0.55(0.3,0.94)*	.034
Alcohol Intake					
No	111(41.6)	156(58.4)	1	1	
Yes	17(24.6)	52(75.4)	2.2(1.1, 3.96)*	1.5(0.75,3.0)	.343
Triglyceride					
Normal (<150)	89(48.9)	93(51.1)	1	1	
High(≥150)	39(25.3)	115(74.7)	2.8(1.77,4.49)***	2.29(1.25,4.2)**	.005
LDL					
Normal (<130)	120(43.8)	154(56.2)	1	1	
High(≥130)	8(12.9)	54(87.1)	5.26(2.4,11.5)***	4.1(1.48,11.4)**	.001
Glucometer use					
Yes	80(47.6)	88(52.4)	1	1	
No	48(28.6)	120(71.4)	2.3(1.45,3.57)***	2.7(1.58,4.64)***	.000
T. cholesterol					
Normal (<200)	114(43.8)	146(56.2)	1	1	
High (≥200)	14(18.4)	62(81.6)	3.45(1.84,6.49)***	1.2(0.490,2.94)	.690
Hypertension					
No	57(33.9)	111(66.1)	1	1	
Yes	71(42.5)	97(57.7)	1.4(.96,2.219) *	1.4(.83,2.57)	.189

COR: Crude Odds Ratio; AOR: Adjusted Odds Ratio; Significant at: * p-value<0.05; **p-value<0.01; ***p-value<0.001; LDL- Low-Density Lipoprotein.

5. DISCUSSION

Diabetes is a chronic disease significantly affecting the quality of life of many people (36). Its prevalence rate is increasing in epidemic proportion in the globe (65). DM incidence is predicted to increase from 2.8% in 2000 to 4.4% in 2030 across the world of all age-groups (65). In the present study, glycemic control and its associated factors among glucometer user and non-glucometer user were evaluated in DM Subjects.

In this study, 208(61.9%) of the study subjects were poor glycemic control. This finding was comparable to studies conducted among DM subjects in Gondar Referral Hospital, Ethiopia, 64.7% (44), Jima, Ethiopia 58.2% (45) and Jordan 65.1% (38). However, the current study was lower than other studies conducted in India, Cameroon and Saudi Arabia (74%, 78.6%, and 78% respectively) (39, 40, 49).

The differences in variation may be explained by the differences in study designs, characteristics of the study populations, and the types of treatment facilities. Furthermore, differences in race and ethnicity of the studied populations, dosage for oral medication, compliance with regimens, self-monitoring of blood glucose, and socioeconomic status may differ by race/ethnic group leading to greater improvements in control in some groups but not in others.

Furthermore, this study showed a higher proportion of poor glycemic control than the study conducted in Ambo Hospital, Ethiopia, which showed 50% poor glycemic control (46). The discrepancy between the findings of the current study and Ambo might be explained by the fact that our study used the recommended test for glycemic control, the HbA1c test, whereas the Ambo study used the FBG test for Glycemic control. Moreover, the Ambo study included only Type 2 DM patients (46).

In this study Poor glycemic control was significantly higher in non-glucometer users (71.4%) than glucometer users (52.4%) (P-value <0.001). This finding was consistent with the studies conducted in Jamaica and Jordan which showed the poor glycemic control proportion among glucometer users were 52.5% (43) and 51.1% (26) respectively. Similarly, the poor glycemic

control among non-glucometer users was higher than glucometer-users in this studies, in Jamiaica 61.9% (43) and Jordan 71.4% (26). However, in this study, the proportion of poor glycemic control among glucometer user was higher than a study conducted in Italy 38.1% (42). The difference might be explained, socioeconomic status may influence diabetes management and control since it is often associated with access to health care, healthcare utilization, use of medication, and access to good nutrition.

The poor glycemic control found in this study was similar to the previous study in Jordan which was 71.4% among non-glucometer users (26). However, the current study was higher than a study conducted in Jamaica 61.9% among non-glucometer users (43). On the other hand, this study was lower than other study reported the proportion of patients with poor glycemic control among non-glucometer user in Italy 80% (42). The difference might be explained due to the difference in study design, lifestyle, and socioeconomic status may differ by race/ethnic group leading to greater improvements in control in some groups but not in others.

In this study, non-glucometer users were significantly associated with the poor glycemic control 71.4%. This finding is similar to a study conducted in Germany (47), Jordan(38), Jamaica (43) and Hawasa, South Ethiopia (61). Various studies have shown that glucometer use was associated with better glycemic control, improved medication compliance and increased the frequency of visit to health institution (47, 48). However, the controversial result was reported from Italy where SMBG frequency $\geq$ 1 time per day has been shown significantly associated with higher HbA1c, distress, worries and depressive symptoms in non-insulin treated DM patients (66).

In this study, Participants who were at age group less than 25 years had higher odds of poor glycemic control compared to greater than or equal to 25 years old. The finding that younger age was associated with poor glycemic control is congruent with similar studies conducted San Diego, USA(53), Netherlands(52), Iraq(50) and Gondar, Ethiopia(44). They might be more likely to pay no attention to DM as being important and could be less adherent to medication, lifestyle and diet limitations. On the contrary, older patients might be more motivated to take care of their DM and be more compliant with their medication, regular physical activity and

eat healthy low-calorie diet. Diabetes self-management intervention may help these target patients to maintain their health and quality of life since effective self-management and quality of life are the key outcomes of diabetes self-management education and support.

Like other factors, in this study, DM participants that were in medium income category had 2.5times (AOR=2.5; 95%CI (1.3, 4.89)) higher odds of poor glycemic control than who were on low income category. This finding was similar to a study done in Hariri, Ethiopia (62). This may be due to medium income DM patients were less adherent to self-care than low-income patients.

However, in this study, Participants who were visited DM clinics less than 6 times had 0.55 times(AOR=0.55; 95%CI (0.3, 0.94)) higher odds of poor glycemic control compared to more or equals to 6 times visited in the past six months. This study was consistent to study conducted in Gondar Referral Hospital (44). This indicates that frequently visiting DM clinic has better counseling and teaching to DM patients, adherence to medication and lifestyle change.

In the present study**,** high triglyceride and LDL level significantly associated with the poor glycaemic control. The finding was similar to a study conducted in Jordan (59) and Hawassa, Southern Ethiopia (58). This might be explained by the fact that chronic entry of fatty acids into b-cells (i.e., b-cell lipotoxicity) is believed to be involved in its pathogenesis and cause pancreatic b-cell failure resulting in poor glycemic control (67).

6. STRENGTHS AND LIMITATIONS

6.1 Limitation of the Study

Study Participants were from a single hospital-based specialty clinic, thus findings could not be generalized beyond this study site.

6.2 Strength of the study

This study determined HbA1-c test which is one of the primary techniques to assess the effectiveness of the management plan on glycemic control.

7. CONCLUSION AND RECOMMENDATIONS

7.1 Conclusion

In this study, a higher proportion of DM subjects had poor glycemic control (61.9%). The poor glycemic control was significantly higher in non-glucometer users (71.4%) than glucometer users (52.4%) for SMBG. The finding obtained from multivariate logistic regression analysis suggest that, age, income, the number of visits, the level of triglyceride, the level of low-density lipoprotein, and non-glucometer users were significantly associated with the poor glycemic control. In fact, glucometer use is associated with lower HbA1c and decreased odds of having poor glycaemic control.

7.2 Recommendations

- There should be periodic assessment of blood glucose monitoring among glucometer user and non-user DM patients.
- Using glucometer for SMBG may, therefore, be useful in achieving glycemic control and should be considered by healthcare practitioners as part of DM management and initiate DM patients to use a glucometer for SMBG. .
- Implementation of HbA1C measurement in the routine follow up of DM patients as a tool for estimation of the long-term diabetes control is highly recommended.
- Further longitudinal studies should be done to identify determinant factors
- The stake holders should be give attention for the availability of glucometers and strips with affordable price for DM patients.

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9. ANNEXES

Annex 1 .English version of information sheet, consent and questionnaire

Annex 1.1 Subject information sheet

Greetings:

My name is _____ I am working with Seifu Mideksa who is currently a post graduate student in University of Gondar, School of Biomedical and Laboratory Sciences, Department of Clinical Chemistry.

The objective of this study is to assess Glycemic control and its associated factors among glucometer user and non-user diabetes mellitus patients at Ayder Comprehensive Specialized Hospital, Mekelle, Northern, Ethiopia. The research is assessing these issues in DM patients like you thereby major factors contributing to anti-DM medication dose and blood glucose level control. You will be asked to fill a questionnaire that will help in investigating the issues. Then venous blood sample 3ml-5ml will be collected by laboratory technologist and the sample will be taken to the laboratory for serum glucose measurement and lipid profile.

Risk during study: There is no risk and serious invasive procedure at the beginning as well as at the end of the study except a minimal pain during sample collection.

Benefit/compensation: In taking part to this study, you are not going to be compensated too, rather the findings from this study will enable us, we hope, to improve DM care outcomes in general, and hence you will be benefited then. Also, you will be know your current HbA1c, FBS, and lipid profile without any payment.

It is only through chance that you became part of the study like others; otherwise, if you do not want to be part of the study, you can refuse to participate. In doing so, you will not going to lose any service that you are getting from the Hospital. I will be very grateful if you are going to be willing to participate in this study and hence we, together can do something positive towards DM care outcomes. Finally, it is my great pleasure to forward you deepest gratitude in advance for your kind cooperation you are going to have during the interview by giving your time with genuine information to me. Once again, I am assuring you, by any means, your

confidentially will not be broken and be kept secret and the data generated will be used for the purpose of this research only.

Annex 1.2 Consent Form

Considering the information you get from the general information sheet, Are you Comfortable to participate in this study? 1. If yes, I will continue 2. If no, I will skip to other participant after writing the reasons of refusal

Respondent

Signature _____Date_____

Interviewer

Name_____ Signature_____

Questionnaires number_____

Date of interview_____ Starting time_____ Completed_____

Result of interview A) Completed B) Not completed C) Partially completed D) Refused

For any information or question

Contact person and address

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Annex 1.3 English versions Questionnaire

Questionnaire Identification Number_____

Address: city/Sub city _____ Worda _____Medical Card Number_____

Title: Glycemic control and its associated factors among glucometer user and non-user diabetes mellitus patients

No	1.Socio-demographic and clinical characteristics	Response classification	Code
101	Sex of the respondents	A. Male	0
		B. Female	1
102	Age	----------	
103	What is your last level of education?	A. Unable to read and write	0
		B. Read and write	1
		C. Primary(Grade 1-8)	2
		D. Secondry(Grade 9-12)	3
		E. College and above	4
104	What is your current occupation?	A.Student	0
		B. Government employee	1
		C. Private enterprise	2
		Employee	3
		D. Merchant	4
		E. Housewife	5
		F. unemployed	6
105	Residence	A. urban	0
		B. rural	1

106	How much income you earn Monthly? (Ethiopian Birr)--------		
107	Marital status	A. Single	0
		B. Married	1
		C. Divorced	2
		D. widowed	3
108	Do you have history of DM in your family?	A. Yes	0
		B .No	1
		C. don't know	3
109	Types of DM	A. Type I	0
		B. Type II	1
		C. Unknown	2
110	Duration of DM in year _____		
111	Types of diabetes management	A. Insulin	0
		B. OHA/tabs	1
		C. Insulin & OHA	2
		D. Diet only	3
112	Regular exercise	A .yes	0
		B .No	1
113	Do you drink alcohol?	A .Yes	0
		B. No	1
114	Do you smoke cigarette?	A. Yes	0

		B. NO	1
115	Do you have glucometer at home for SMBG?	A. Yes	0
		B. No	1
116	How many times did you visit DM clinic for the last 6 months?		

_____

Annex 1.4 Anthropometric measurements code no. _____

1. BMI weight _____kg

   Height _____m

   $= W/H^2$

   _____Kg/m^2

   A. low B. Normal C. over weight D. obesity

2. Blood pressure BP _____mm/hg

   Hypertensive A. yes B. No

Annex 2.5 Laboratory test code no. _____

1. Fast blood glucose(FBS) _____

   HbA1c _____

   A. good glycemic control HbA1c <7% or FBS <130mg/dl B. poor glycemic control HbA1c ≥ 7% or FBS ≥ 130mg/dl

2. Lipid profile

   Total cholesterol _____ (≥200mg/dl)

   Triglyceride _____ (≥150mg/dl)

   HDL-C for male _____(<40mg/dl)

HDL-C for female _____(<50mg/dl

LDL-C _____ (≥130mg/dl)

Dyslipidemia A. yes B. No

Name of data collector _____ Signature _____

Name of Supervisor _____ Signature _____

Thank you very much for your giving your precious time and your collaboration!

Annex 2. Laboratory procedures and test principles

Procedure for Determination of HbA1c, Glucose and lipid profile using HumaMeter A1c and Clinical chemistry analyzer

1. Label tubes with the participants' code number. (Labeling can also be done immediately after the specimen is obtained).
2. Explain the blood drawing procedure to the participant and reassure
3. Wear the rubber gloves and make the patient a comfortable position
4. Prepare the syringe and needle
5. Tie the tourniquet around the arm of the patient just above the bend in the elbow. The tourniquet should be positioned 7.5cm to 10cm above the puncture site
6. Tell the patient to clench his/her fist
7. using the tip of the index finger examine the phlebotomy site, feel the vein, and decide exactly where to place the puncture
8. Disinfect the phlebotomy site by swabbing the skin in small outward circles with alcohol swab or cotton wool soaked in isopropyl alcohol. Do not touch the prepared puncture site with your fingers after disinfecting the skin
9. Insert the needle directly into the vein and withdraw venous blood of approximately 5ml transfer the blood in to EDTA test tube about 2ml for HbA1c test and about 3ml into SST test tube slowly for FBS and lipid profiles tests.
10. Tell the patient to open his/her clenched fist
11. Release the tourniquet
12. Withdraw the needle from the vein and cover the puncture site cotton swab and hold (or have the subject hold) pressure at the puncture site for 3 minutes or until adequate haemostasis is visible.
13. Properly discard the used materials in a safe container and tell the subject to do so if handled the cotton swabs to stop the bleeding
14. The venous blood sample taken to the laboratory within 30 minutes and centrifuged at 5000rpm for 5 minutes to obtain the serum
15. Calibrate Chemistry Analyzer using calibrator and run the control N and control P
16. Check the Quality control results whether passed or fails if passed

17. Test EDTA blood sample for HbA1c

18. Test serum sample for FBS and lipid profile

19. Record the result

N.B. we were strictly follow standard operation procedures (SOPs) and Manufacturer's instructions.

The specimens were analyzed using PENTRA ABX 400 (Horiba ABX Diagnostics France) for FBS and Lipid profiles and HumaMeter A1c (HUMAN Diagnostics for HbA1c determination

HbA1c

Principle

The Humameter A1c regent KIT combines the chemical binding of boronate to glycated hemoglobin with the fluorescent quenching effect that this binding exerts on a fluorescent marker bound to the boronate molecule . the total hemoglobin concentration is determined from the initial decrease in the fluorescent signal. The fluorescent boronate conjugate binds to the glycated hemoglobin, which is measured by monitoring a decrease in the fluorescence of the active ingredient. The ratio of glycated hemoglobin to total hemoglobin is determined and the result is presented in up to two user selectable units: % DCCT(Diabetes control & complication Trial),mmol/mol IFCC (international Federationof clinical Chemistry).

Mmol/mol=(% DCCT-2.15)*10.929

Clinical Significance

HbA1c is formed in two steps by the nonenzymatic reaction of glucose with the N-terminal amino group of the β-chain of normal adult Hb (HbA). The first step is reversible and yields labile HbA1c. This slowly rearranges in the second reaction step to yield stable HbA1c. In erythrocytes the relative amount of HbA converted to stable HbA1c increases with the average concentration of glucose in the blood. The conversion to stable HbA1c is limited by the erythrocyte's life span of approximately 100 to 120 days. As a result, HbA1c reflects the average blood glucose level during the preceding two to three months. HbA1c is thus suitable to monitor long-term blood glucose control in individuals with diabetes mellitus. More recent glucose levels have a greater influence on the HbA1c level.

The risk of diabetic complications, such as diabetic nephropathy and retinopathy increases with poor metabolic control. In accordance with its function as an indicator for the mean blood glucose level, HbA1c predicts the development of diabetic complications

Testing Procedure:

1. Check the temperature indicator on the box before taking a cartridge out. If red, do not use.
2. Refrigerated cartridges should be warmed to room temperature for 10 minutes before use.
3. When a cartridge package is opened, the cartridge must be used within one hour.
   - Check the cartridge and do not use it:
     - if the cartridge is damaged,
     - if the flexible cartridge pull-tab is loose or missing, or
     - If the desiccant is missing or loose desiccant particles are found inside the foil pouch.
4. Room temperature must be between 15^{0c} and 30°c. Do not test if temperature exceeds this range. Room temperature must be recorded on the test log for each test that is done.
5. Allow the instrument enough time to warm up at the beginning of the day.
6. Pass cartridge through reader. A beep sound indicates a successful scan
7. Fill capillary holder with blood (1 microliter from EDTA blood). Wipe outside of capillary tube.
8. If blood contacts the plastic part of the capillary holder, discard the holder and use another one.
9. Insert holder into the reagent cartridge with the rounded side of the holder to the outside.
10. Hold the cartridge with the foil to the left, and insert cartridge into instrument until it snaps into place.
11. Remove the tab and foil from the cartridge.
12. Close the door on the instrument. Reaction is completed in 6 minutes.

13. Read percent HbAlc before removing the cartridge.
    - The range of the instrument is 4 to 15.0%.
    - The result is displayed as percent HbA1c.
    - Results proceeded by a < sign indicates a level below the range and a > indicates a level above the range, and should be recorded as such.
14. Record the result in the testing log, and in the patient's chart. All results are reported to the physician or advance practice nurse immediately.
15. Remove the cartridge by pushing down on the gray tab while sliding the cartridge to the right, toward the gray tab—then lift the cartridge out of the instrument and discard it in a biohazard container.

Calculations

None. The result is displayed as percent HbA1*c*.

Reporting Results

Reference Range: 4.2% to 6.5% HbA1c

Good glycemic control if < 7% HbA1c according to ADA

Poor glycemic control if ≥ HbA1c 7% according to ADA

Glucose

Principle of glucose oxidase method: Glucose level will be determined by an enzymatic spectrophotometric glucose oxidase method. The basic principle is that, Glucose is oxidized by glucose oxidase (GOD) enzyme to produce gluconate and hydrogen peroxide (H2O2). The H2O2 is then oxidatively coupled with 4 amino-antipyrene (4-AAP) and phenol in the presence of peroxidase (POD) enzyme to yield a red quinoeimine dye that is measured at 505 nm with a spectrophotometer. The absorbance at 505 nm is proportional to concentration of glucose in the sample. The method has linearity from bb0.0126 mmol/l (0.23 mg/dl) to 27.5 mmol/l (500 mg/dl).

Glucose +2H2O + O2 GOD Gluconate + H2O2

2H2O2 + 4-AAP+ Phenol POD Quinoeimine Dye + 4H2O

Absorbance of the colored solution is directly proportional to the glucose concentration when measured at 505 nm.

Triglyceride

Test principle:

Enzymatic colorimetric method (GPO/PAP) with glycerol phosphate oxidase and 4 amino phenazone.b

Triglycerides are hydrolyzed by lipoprotein lipase (LPL) to glycerol and fatty acids. Glycerol is then phosphorylated to glycerol-3-phosphate by ATP in a reaction catalyzed by glycerol kinase (GK). The oxidation of glycerol-3-phosphate is catalyzed by glycerol phosphate oxidase (GPO) to form dihydroacetone phosphate and hydrogen peroxide (H_2O_2). In the presence of peroxidase (POD), hydrogen peroxide affects the oxidative coupling of 4-chlorophenol and 4-aminophenazone to form a red colored quinoneimine dye, which is measured at 512 nm. The increase in absorbance is directly proportional to the concentration of triglycerides in the sample.

Triglycerides $\xrightarrow{LPL}$ glycerol + fatty acids

Glycerol + ATP $\xrightarrow{GK}$ glycerol-3-phosphate + ADP

Glycerol-3-phosphate + O_2 $\xrightarrow{GPO}$ dihydroacetone phosphate + H_2O_2.

$2H_2O_2$ + 4-aminophenazone $\xrightarrow{POD}$ quinoneimine dye + 4-chlorophenol + $4H_2O$

Cholesterol

Test principle:

Enzymatic colorimetric method (CHOD/PAP) with cholesterol esterase, cholesterol oxidase, and 4-aminoantipyrine.

Cholesterol esterase (CE) hydrolyzes cholesterol esters to form free cholesterol and free fatty acids. Cholesterol oxidase (CHOD) then catalyzes the oxidation of cholesterol to form cholest-4-ene-3-one and H_2O_2. In the presence of peroxidase (POD), the hydrogen peroxide formed affects the oxidative coupling of phenol and 4-amino-antipyrine(4-AAP) to form a red colored quinoneimine dye. The color intensity of the red quinoneimine dye formed is directly proportional to the cholesterol concentration. It is determined by measuring the increase in absorbance at 520 nm.

Cholesterol esters + H2O *CE*→ cholesterol + fatty acids

Cholesterol + O2 *CHOD*→ cholest-4-ene-3-one + H2O2

2H2O2 + 4-AAP+ phenol *POD*→ quinoneimine dye +4 H2O

HDL-Cholesterol:

Test principle:

Homogeneous enzymatic colorimetric assay

In the presence of magnesium sulfate and dextran sulfate, water-soluble complexes with LDL, VLDL, and chylomicrons are formed which are resistant to Poly Ethylene Glycol (PEG)-modified enzymes. The cholesterol concentration of HDL-cholesterol is determined enzymatically by cholesterol esterase and cholesterol oxidase coupled with PEG to the amino groups (approximately 40%). Cholesterol esters are broken down quantitatively into free cholesterol and fatty acids by cholesterol esterase. In the presence of oxygen, cholesterol is oxidized by cholesterol oxidase to 4-cholestenone and hydrogen peroxide. The color intensity of the blue quinoneimine dye formed is directly proportional to the HDL-cholesterol concentration. It is determined by measuring the increase in absorbance at 583 nm.

HDL-cholesterol esters + H2O–PEG cholesterol esterase→ HDL-cholesterol + RCOOH

HDL-cholesterol + O2–PEG-cholesterol oxidae→4-cholestenone + H2O2

2 H2O2 + 4-aminoantipyrine + HSDA+ Hperoxidase→ purple blue pigment + 4 H2O

LDL-Cholesterol:

Test principle:

Homogeneous enzymatic colorimetric assay

This automated method for the direct determination of LDL-cholesterol takes advantage of the selective micellary solubilization of LDL-cholesterol by a nonionic detergent and the interaction of a sugar compound and lipoproteins (VLDL and chylomicrons). When a detergent is included in the enzymatic method for cholesterol determination (cholesterol esterase and cholesterol oxidase coupling reaction), the relative reactivities of cholesterol in the lipoprotein fractions increase in this order: HDL < chylomicrons < VLDL < LDL. In the presence of Mg++, a sugar compound markedly reduces the enzymatic reaction of the cholesterol measurement in VLDL and chylomicrons. The combination of a sugar compound with detergent enables the selective determination of LDL-cholesterol in the serum. In the presence

of oxygen, cholesterol is oxidized by cholesterol oxidase to 4-cholestenone and hydrogen peroxide. The color intensity of the blue quinoneimine dye formed is directly proportional to the LDL-cholesterol concentration. It is determined by measuring the increase in absorbance at 583 nm.

LDL-cholesterol ester + H2O–detergent–cholesterolesterase→ cholesterol + free fatty acid (selective micellarysolubilization)

LDL-cholesterol + O2–cholesterol oxidase→4-cholestenone+ H2O2

2 H2O2 + 4-aminoantipyrine + HSDA+ H+H2O2–peroxidase→ purple blue pigment +5 H2O

Annex 3. Amharic version participants information sheet, consent and questionnaire

ጎንደር ዩኒቨርሲቲ፤ ህክምናና ጤና ሳይንስ ኮሌጅ፤ ባዮሜዲካልና ላቦራቶሪ ሳይንስ ት/ቤት፤ ክሊንካል ኪሚስትሪ ት/ክፍል

የተጠያቂው / መላሾች የመረጃ ቅፅ እንደምን አደሩ / ዋሉ ። ስሜ ---------- ይባላል። ከዚህ የመጣሁት የጎንደር ዩኒቨርሲቲ፤ ህክምናና ጤና ሳይንስ ኮሌጅ፤ ባዮሜዲካልና ላቦራቶሪ ሳይንሥ ት/ቤት፤ ክሊንካል ኬሚስትሪ ት/ክፍል የሁለተኛ ዲግሪ ተማሪ የሆነውን ሰይፉ ሚደቅሳ ወከዬ ነው። ሁለተኛ ዲግሪዉን ለመመረቅ የስኳር ህመምተኞች በደማቸው ውስጥ የሚገኘውን የስኳር መጠን እንዴት እየተቆጣጠሩት እንደሆነ የራሳቸው የመርመሪያ መሳሪያ(ጉሉኮሜትር) በቤታቸው በሚጠቀሙ እና በማይጠቀሙ መካከል ያለውን ልዩነት እና ተያያዥ ወሳኝ ጉዳዮችን በተመለከተ በአይደር አጠቃላይ ስፔሻላይዝድ ሆስፒታል የስኳር ህመም ክትትል በሚያደርጉ ህመምተኞች ከጎንደር ዩኒቨርሲቲ እና ከአይደር አጠቃለቀይ ስፔሻላይዝድ ሆስፒታል ፍቃድ አግኝቶ ምርምር ጥናት እየሰራ ነው። እርስዎ የተመረጡት በዚህ ተቋም የስኳር ህመም ክትትል በማድረግ ላይ ስለሚገኙ እና በእድል ወይም በእጣ ነው። በአጠቃላይ እድሜያቸው 18 እና ከዚህ አመት በላይ የሆኑ ስኳር ህመምተኞች ይሳተፋሉ። የእርስዎ ተሳትፎ ሙሉ በሙሉ የእርስዎ ፍቃደኝነት ላይ የተመሰረተና በጥናቱ መሳተፍ ያለመሳተፍ መብት አሎዎት። ለመሳተፍ ፈቃደኛ ከሆኑ በኋላም በፈለጉት ጊዜ ማቋረጥ ወይም ማቆም ይችላሉ። በጥናቱ ባለመሳተፍዎ የሚደርስብዎ ጉዳት የለም። በጥናቱ ለመሳተፍ ከተስማሙ ስለራሰዎ የግል ሁኔታ እና ተያያዥ ጉዳዮች እስከ 15 ደቂቃ ሊወስድ የሚችል የተወሰኑ ጥያቄዎች እንጠይቆታለን። በመቀጠል የሰለጠነ ነርስ ወይም የላብራቶሪ ባለሞያ ከክንዶ ላይ ከ3ml-5ml ደም ለስኳር እና የስብ መጠን ለማወቅ ለላብራቶሪ ምርመራ ይወሰዳል።

በጥናቱ በመሳተፎ ደም በሚቀዳበት ጊዜ ከሚሰማዎ ትንሽ ህመም በስተቀር የሚደርስብዎ ጉዳት የለም።በዚህ ጥናት በመሳተፎ በቀጥታ የሚያገኙት ጥቅም(ገንዘብ) ባይኖርም በጥናቱ በሚገኙ ግኝቶች የስኳር ህመም ህክምና ውጤትን በተመለከተ በተወሰነ መልኩ ለማሻሻል በመገመት የጥቅሙ ተጀዳሽ ይሆናሉ ብለን እናምናለን። ከጥናቱ የስኳር ህመምተኞች የስኳር መመርመሪያ መሳሪያ(ጉሉኮሜትር)አጠቃቀም ልምድዎን እንዴት ማሻሻል እንዳለብዎ ይረዳሉ። ከዚህም በተጨማሪ የጥናቱ ውጤት የስኳር ህመምተኞች የግል መመርመሪያ መሳሪያቸውን በመጠቀም በደማቸው ውስጥ የሚገኘውን የስኳር መጠን በትክክለኛው መጠን ለመቆጣጠር እና የሚወስዱትን መድሀኒት መጠን ለመመጠን ልምድ ይበልጥ ለማሻሻል ለሌሎች ተመራማሪዎች በዚህ ዙሪያ ለሚሰሩ አካላት እንደመነሻ ያገለግላል።

ላላማውን ተረድተውና ጊዜውትን ሰውተው በዚህ ጥናት ለመሳተፍና እውነተኛ መረጃ ለመስጠት ፍቃደኛ በመሆኖው በቅድሚያ እናመሰግናለን።ማንኛውም የሚሰጡት መረጃ ለምርምሩ አላማ ብቻ የሚውልና ሚስጥርነቱውም የሚጠበቅ መሆኑን ላረጋግጥልዎ እወዳለሁ።

በድጋሚ አመሰግናለሁ!

Annex 3.2: Amharic version subject informed consent form

የስምምነት መጠየቂያ/ማረጋገጫ ቅፅ

ከላይ በሰጠሆዎት መረጃ መሰረት በዚህ ጥናት ለመሳተፍ ፍቃደኛ ነዎት 1) አዎ (ቃለ መጠይቁን ቀጥሉ)

2) አይደለሁም (ምክንያቱን ፅፈህ ወደሚቀጥለዉ ተሳታፊ እለፍ)

መላሽ/ተሳታፊ

ፊርማ _____ ቀን _____

ጠያቂ

ስም _____ ፊርማ _____

የመጠይቁ ቁጥር_____

መጠይቁ የተካሄደበት ቀን _____ መጠይቁ የተጀመረበት ሰአት _____የተጠናቀቀበት ሰአት _____

የቃለ መጠይቁ ዉጤት 1) ሙለ በሙሉ የተሞላ 2)በከፊል የተሞላ 3) ምንም ያልተሞላ

በተቆጣጣሪዎች ተረጋግጧል ::ስም _____ፊርማ _____

ለማንኛውም አይነት ጥያቄ እና መረጃ ዋና አጥኚውን ወይም አማካሪዎችን ማነጋገር ይችላሉ፡

የዋና ተመራማሪው አድራሻ፤

ሰይፉ ሚደቅሳ

ኢ-ሜይ ል ፣ seifumid2000@yahoo.com

ስ ል ክ ፣ +251-911-911692/0914132251

አማካሪዎች

ሀብታሙ ወንድይፍራው (MSc)

ስልክ ቁጥር፡ 0910818289

ኢ-ሜይል :habtamuw97@gmail.com

ስንታየው አምባቸው (MSc)

ስልክ ቁጥር፡ 0938279709

ኢ-ሜይል፡ sinte.ambachew@gmail.com

ትእዛዝ ፤ተሳታፊዎቹ የሚሰጡትን ማንኛዉንም መልስ ከተሰጡት አማራጮች ዉስጥ ለይተህ አክብብ ወይም በቁጥር አስቀምጥ::

Annex 3.3 Questionnaire (Amharic version)

ክፍል አንድ፡ ማህበራዊ ኢኮኖሚያዊ ሁኔታ እና ከስኳር ህመም ጋር ተያያዥ ጉዳዮች መጠይቅ

ተ.ቁ	ጥያቄዎች	አማራጭ መልሶች
101	እድሜ----------(በቁጥር ይፃፍ)	
102	ጾታ	1. ወንድ 2. ሴት
103	የትምህርት ደረጃ	1. መፃፍና ማንበብ የማይችሉ 2. መፃፍና ማንበብ የሚችሉ 3. አንደኛ ደረጃ (1-8) 4. ሁለተኛ ደረጃ(9-12) 5. ኮሌጅ/ዩንቨርስቲና ከዚያ በላይ
104	የስራሁኔታ(ከአንድ በላይ መልስ መስጠት ይችላሉ)	1. ተማሪ 2. የመንግስት ስራተኛ 3. የግል ስራ 4.ነጋዴ 5. ስራ የሌለው 6. ቤት እመቤት 7. ሌላ ካለው ይጠቀስ----------
105	የጋብቻ ሁኔታ	1. ያገባ 2. ያላገባ 3. የፈታ/በሞት የተለየ
106	የቤተሰብ ወርሃዊ ገቢ (በብር) _____ (በቁጥር ይፃፍ)	
	የመኖሪያ ቦታ	1. ከተማ

107		2. ገጠር
108	በቤተሰብ ውስጥ በህክምና የተረጋገጠ የስኳር በሽታ ያለበት አለን?	1. አዎ 2. የለም 3. አላውቅም
109	የስኳር ህመም ዐይነት ያውቁታል? ካላወቁት ከካርዳቸው ላይ ይመልከቱ	1.ዓይነት አንድ 2. ዓይነት ሁለት 3.አላውቅም
110	የስኳር ህመምተኛ መሆኖን ካወቁ ምን ያህል አመት አድርገዋል?_____	
111	በደም ውስጥ ያለውን የስኳር መጠን ለመቆጣጠር የሚወስዱት መድሓኒት?	1. እንሱሊን በመርፌ 2. በአፍ የሚወሰድ ክኒኒ 3. ሁለቱንም 4. በምግብ ብቻ መቆጣጠር
112	የሰውነት እንቅስቃሴ አዘውትረው ያደርጋሉ?	1. አዎ 2. አላደርግም
113	አልኮል ይጠጣሉ?	1. አዎ 2.አልጠጣም
114	ሲጋራ ያጨሳሉ?	1. አዎ 2. አላጨስም
115	በቤቶ የግሎ የስኳር መመርመሪያ መሳሪያ(ጉሉኮሜትር) አሎት?	1. አለኝ 2. የለኝም
116	በዚህ ስድስት ወር ውስጥ ምን ያህል ጊዜ የስኳር ህመም ክትትል ለማድረግ ወደዚህ ሆስፒታል መተዋል? ----------	

ክፍል ሶስት፡የላብራቶሪ ምርመራ ውጤት የመለያ ቁጥር----------

1. ምግብ ሳይበላ በደም ውስጥ ያለው የስኳር መጠን(FBS)

   FBS _____

   HA1c _____

3. ምግብ ሳይበላ በደም ውስጥ ያለው የስብ መጠን Lipid profile

   Total cholesterol _____

   Triglyceride _____

   HDL-C _____

   LDL-C _____

Dyslipidemia A. አዎን B. ኖርማል

III. Anthropometric measurements code no._____

1. የሰውነት ክብደት ጠቋሚ (BMI) ክብደት(weight) _____kg

   ቁመት(Hight)_____m

   = W/H^2 (ክ/ቁ$^{2)}$

   _____Kg/m^2

   A. ዝቅተኛ B. ኖርማል C. ወፍራም D. በጣም ወፍራም

2. የደም ግፊት መጠን (Blood pressure)BP _____mm/hg

   የደም ግፊት መጠን (Hypertensive) A. አለው B. ኖርማል

መረጃውን የሰበሰበው ስም_____ ቀን----------ፊርማ-----

የተቆጣጣሪው ስም---------- ቀን ---------- ፊርማ----------

ወርቃማ ጊዜውን ሰውተው ለጥናቱ ስለተባበሩን ከልብ እናመሰግናለን!

Annex 4: Tigrigna version participants information sheet, consent and questionnaire form

ናይ ተሓተትቲ/ መለስቲ ሓበሬታ ቅጥዒከመይሓዲርኩም / ውዒልኩም::ሽመይ ---------- ይበሃል። ናብዚ ዝመፃእኩ ናይ ጎንደር ዩኒቨርሲቲ ሕክምናን ጥዕና ሳይንስን ኮሌጅ፤ ባዮሜዲካልን ላቦራቶሪ ሳይንስ ት/ቤት፤ ክሊንካል ኬሚስትሪ ት/ክፍሊ ናይ ካልኣይ ዲግሪ ተማሃሪ ዝኮነ ሰይፉ ሚደቅሳ ወኪለእየ:: ካልኣይ ዲግሪ ንክምረቅ ናይ ሽኮር ሕሙማት አብደሞ ምውሽጢ ዝርከብ ናይ ሽኮር መጠን ከመይ እንዳተቆፃፀርዎከም ዝሆነ ናይ ባዕሎም መመርመሪ መሳሪሒ(ጉሉኮሜትር)አብ ገዝኦም ዝጥቀሙን ዘይጥቀሙን ሞንጎ ዘሎ አፈላላይን ተተሓሓዝቲ ወሰንቲ ጉዳያትን ብዝምልከት ኣብ ዓይደር አጠቃላይ ስፔሻላይዝድ ሆስፒታል ናይ ሽኮር ሕማም ክትትል ዝገብሩ ሕሙማት ካብ ጎንደር ዩኒቨርሲቲ ን አጠቃላይ ስፔሻላይዝድ ሆስፒታል ንፍቃድ ረኪቡ ምርምር እናሰርሐ አዩ::

ንሶም/ንሰ ንዝተመረፅሉ/ፃሉኣ ብዚ ትካል ናይ ሕማም ሽኮር ክትትል ኣብምግባር ስለዝረከቡን ብዕድል ወይከዓ ብዕፃ እዩ:: ብሓፈሻ ዕድሚኦም 18ን ካብኡ ንላዕሊን ዝኮኑ ናይሽኮር ሕሙማት ይሳተፉ እዮም:: ናቶም ተሳትፎ ሙለእ ብሙሉእ ብናቶም ፍቕደኝነት ዝተመስረተ ኮይኑ አብዚ ፅንዓት ናይምስታፍ ንዘይምስታፍን መሰል አለዎም ንምስታፍ ፍቕደኛ ድሕሪምእዉን አብዝደለይዎ ግዜ ምቁራፅ ይክእሉ:: ኣብዚ ፅንዓት ብዘይምስታፍኩም ዝበፅሐኩም ጉድኣት የለን::ኣብዚ ፅንዓት ንምስታፍ ተተስማዕሚዕም ብዛዕባኩም ዉልቀ ጉዳይን ናይሽኮር ህማም ንተተሓሓዝቲ ጉዳያት ዝምልከት ክሳብ 15 ደቂቃከወስዱ ዝእሉ ዝተወሰኑ ሕቶታት ክንሓቶምኢና:: ካብኡ ብምቕፃል ብዝሰልጠነ ነርስ ወይ ላብራቶሪ ባዓልሞያ ካብኢዶም 5 ሚሊሊትር ደም ንሽኮርን ናይ ስብሒ መጠንን ንላብራቶሪ ምርመራ ክቕድሑእዮም::

ኣብዚ ፅንዓት ብምስታፍኩም ደም ኣብዝውሰደሉ ጊዜ ካብ ዝስመዖም ንእሽተይ ሕማም ወፃኢ ዝበፅሖም ጉድኣት የለን:: ኣብዚ ፅንዓት ብምስታፍኩም ብቕጥታ ዝረከቡዎ ጥቕሚ (ገንዘብ) የለን ኮይኑ ግና በዚ ፅንዓት ኣቢሎም ዝርከቡ ዉፅኢት ናይ ሕማም ሽኮር ሕክምና ውፅኢት ብዝምልከት ብዝተወሰነ መልክዑ ንምምሕያሽ ብምግማት ናይዚ ጥቕሚ ተቃደስቲ ክትእዮኑም ኢልና ንኣምን:: ካብዚ ፅንዓት ናይ ሽኮር ሕሙማት ናይ ሽኮር መመርመሪ መሳሪሒ(ጉሉኮሜትር) አጠቃቀማ ልምዶም ከመይ ከመሓይሹከም ዘለዎም ይፈልጡ ካብዚ ብተወሳኪ ናይዚ ፅንዓት ውፅኢት ናይ ሽኮር ሕሙማት ናይ ባዕሎም መመርመሪ መሳርሒ ብምጥቃም አብደሞም ውሽጢ ዝርከብ ናይ ሽኮር መጠንን ምቁፅፃርን ዝወስድዎ መድሓኒት መጠን ንምምጣን ዝበለፀ ልምዲ ንምምሕያሽንን ካልኦት አብዚ ዙርያ ዝሰርሑ ተመራመረቲ አካላት ከምመበገሲ የገልግል::

ናይዚ ፅንዓት ዓላማ ተረዲኦም ጊዜኦም ሰዊኦም አብዚ ፅንዓት ንምስታፍ ንሓቀኛ ሓበሬታ ንምሃብ ፍቃደኛ ስለዝኮኑ ብቅድሚያ ብጣዕሚ የመስግን:: ኩሉ ዝህበዎ ሓበሬታ ነዚ ፅንዓት ዓላማ ጥራሕ ከምዝውዕል ንሚስጥሩ ዝተሓለወ ምሆኑን ከረጋግፀልኩም ይፎቱ::

ብድጋሚ የቀንየለይ!!

Annex 4. 2 : Tigrigna version subject informed consent form

ናይ ስምምዕነት መሕተቲ/መረጋገፂ ቅጥዒ

ኣብ ላዕሊ ብዝሃብክዎም መረጃ መሰረት ኣብዚ ፅንዓት ንምስታፍ ፍቃደኛ ድዮም?

1) እወ (እቲ ቃለ መሕትት ቀፅል)

2) ኣይኮንኩን (ምክንያቱ ፅሒፍካ ናብ ዝቐፅል ተሳታፋይ ሕለፍ)

ናይ ተሳታፊ

ፌርማ _____ ዕለት_____

ናይሓታቲ

ሽም _____ ፈርማ _____

ናይዚ መሕትት ቁፅሪ_____

ቃለ መሕትት ዝተካየደሉ ዕለት _____ ቃለ መሕትት ዝተጀመረሉ ሰዓት _____ ዝተጠናቐቐሉ ሰዓት _____

ናይ ቃለ መሕትት ውፅኢት 1) ሙሉእ ብሙሉእ ዝተመልአ 2)ብከፊል ዝተመልአ 3) ምንም ዘይተመልአ

ብተቆፃፀርቲ ተረጋጊፁ እዩ። ሽም _____ ፈርማ _____

ንዝኮነ ዓይነት ሕቶን ሓበሬታን ዋና ተመራማሪ ምዝርራብ ይከኣል እዩ።

ናይ ዋና ተመራማሪ አድራሻ

ሰይፉ ሚደቅሳ

ኢ-ሜይል፣ seifumid2000@yahoo.com

ስልኪ፣+251-911-911692

አማካሀሪቲ

ሀብታሙ ወንድይፍራው (MSc)

ስልክ ቁጥር፡ 0910818289

ኢ-ሜይል ፡habtamuw97@gmail.com

ስንታየው አምባቸው (MSc)

ስልክ ቁጥር፡ 0938279709

ኢ-ሜይል፡ sinte.ambachew@gmail.com

ትእዛዝ፤ ተሳተፍቲ ዝህበዎ መልሲ ካብቶም ዝቐረቡ መማረፂ ዉሽጢ ፈሊካ አከብብ ወይ ብቁፅሪ ኣቐምጥ

Annex 5.3 Questionnaire (Tigrigna version)

ክፍሊሓደ፡ ማሕበረሰባዊን ኢኮኖሚያዊን ኩነታትን ምስ ሕማም ሽኮር ተተሓሓዙ ጉዳያት ቃለ መሕትት

ተ.ቁ	ሕቶታት	መማረፂመልስታት	ኮድ
101	ዕድመ----------(ብቁፅሪይፅሓፉ)		
102	ፆታ	1. ተባዕታይ	0
		2. ኣንስተይቲ	1
103	ደረጃ ትምህርቲ	1. .ምንባብን ምፅሓፍን ዘይክእል	0
		2. .ምንባብን ምፅሓፍን ዝክእል	1
		3. .ቀዳማይ ብርኪ(1-8)	2
		4. ካልኣይ ብርኪ(9-12)	3
		5. ኮሌጅ/ዩንቨርስቲን ልዕሊኡን	4
104	ኩነታት ስራሕ (ካብ ሓደን ላዕሊ መልሲ ምሃብ ይከእሉ)	1. ተምሃራይ /ተምሃሪት	0
		2. ናይ መንግስቲ ሰራሕተኛ	1
		3. ናይ ግሊ ስራሕ	2
		4. ነጋዳይ	3
		5. ስራሕ ዘይብሉ	4
		6.በዓልቲ ሓዳር	5
		7. ካሊእ ተሃልዩ ይጠቕስ_____	6
105	ኩነታት ሓዳር	1. ዝተመርዐወ/ዝተመርዐወት	0
		2. ዘይተመርዐወ/ዘይተመርዐወት	1

		3. ዝተፋተሐ/ዝተፋተሐትወይሰብኣያዝሞታ/ሰበይቱዝሞተቶ	2
106	ናይ ስድራ ወርሓዊ አታዊ (ብቅርሺ) _____ (ብቁፅሪ ፀሓፍ)		
107	መንበሪ ቦታ	3. ከተማ	0
		4. ገጠር	1
108	ኣብ ቤተሰብኩም ብሕክምና ዝተረጋገፀ ሕማም ሽኮር ዘለዎ ኣሎዶ ?	1. እወ	0
		2. የለን	1
109	ናይ ሽኮር ዓይነቶም ይፈልጡ ዶ? ተዘይፈሊጦሞ ካብ ካርዶም ይርኣዩ	1. ዓይነት ሓደ	0
		2. ዓይነት ክልተ	1
		3. ኣይፈልጥን	2
110	ሕማም ሽኮር ክምዘለዎም ካብ ዝፈልጡ ክንደይ ዓመት ገይሮም?_____		
111	ኣብደሞም ውሽጢ ንዘሎ ናይሽኮር መጠን ንምቁፅፃር መድሓኒት?	5. እንሱሊንብመርፍእ	0
		6. ብኣፍዝውሰድከኒና	1
		7. ክልቲኡ	2
		8. ብምግቢ ጥራሕ	3
112	ናይ ሰውነት ምንቅስቃስ ኣዘውቲሮም ይገብሩ ዶ?	3. እወ	0
		4. ኣይገብርን	1
113	ኣልኮል ይሰትዩ ዶ?	2. እወ	0
		3. ኣይሰትን	1
114	ሽጋራ ተትክህ ዲኩም?	3. እወ	0
		4. ኣየትክን	1
115		3. እወ	0

	ኣብ ገዝኡም ናይ ውልቆም ናይ ሽኮር መመርመሪ መሳርሒ(ጉሉኮሜትር) ኣለዎም ዶ?	4. የብለይን	1
116	ኣብዚህ 6 ወህሪ ውሽጢ ክንዳ ጊዜ ናይ ሽኮር ህማም ክትትል ንምግባር ኣብዚህ ሆስፒታል መጺሁም? _____		

Annex 5. Declaration

I, the undersigned, declare that this thesis is my own work and that all sources of material used for the thesis have been duly acknowledged.

Name: Seifu Mideksa

Signature:_____

Place of submission: School of Biomedical and Laboratory Sciences, CMHS, University of Gondar.

Date of Submission: _____

This thesis has been submitted for examination with my approval as an advisor.

Name	Signature
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Mr. Sintayehu Ambachew (Msc)	_____

Examiners

Name	Signature	Date
1. Zerihun	_____	_____
2. Belete Biadigo	_____	_____

Annex 6. Assurance of investigator

The undersigned agrees to accept responsibility for the scientific, ethical and technical conduct of the research project and for provision of required progress reports as pre terms and conditions of the research and publications office of the University of Gondar.

Name of the student: Seifu Mideksa

Date: _____ Signature: _____

Approval of the advisors

Advisors

Name	Signature	Date
Mr. Habtamu Wondifraw (Msc)	_____	_____
Mr. Sintayehu Ambachew (Msc)	_____	_____

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2. Belete Biadigo	_____	_____